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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,770	12/20/2001	Bruce J. Mayer	701039-050001	2706

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EXAMINER
SHIBUYA, MARK LANCE

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,770	MAYER ET AL.	
	Examiner	Art Unit	
	Mark Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a fusion protein comprising a protein containing a modular protein binding domain (MPBD), wherein the MPBD is substituted by a single chain antibody, classified in class 424, subclass 134.1.

II. Claims 5 and 6, drawn to genes encoding fusion proteins comprising a protein containing a modular protein binding domain (MPBD), wherein the MPBD is substituted by a single chain antibody, and vectors thereof, classified in class 536, subclass 23.4.

III. Claims 7-10, drawn to a fusion protein comprising a protein containing a binding site that binds to a MPBD, wherein a linear epitope that binds to the MPBD within the binding site is substituted by at least one antigenic epitope that binds to an antibody, classified in class 424, subclass 192.1.

IV. Claims 11 and 12, drawn to genes encoding fusion proteins comprising a protein containing a binding site that binds to a MPBD, wherein a linear epitope that binds to the MPBD within the binding site is substituted by at least one antigenic epitope that binds to an antibody, and vectors thereof, classified in class 536, subclass 23.4.

V. Claims 13-15, drawn to a cell transformed by a vector or vectors, encoding a fusion protein comprising a protein containing a modular protein binding domain (MPBD), wherein the MPBD is substituted by a single chain

antibody and /or encoding a fusion protein comprising a protein containing a binding site that binds to a MPBD, wherein a linear epitope that binds to the MPBD within the binding site is substituted by at least one antigenic epitope that binds to an antibody, classified in class 435, subclass 326.

VI. Claim 16, drawn to a *library* of proteins that contain MPBD and are fused to a single chain antibody, classified in class 424, subclass 134.1.

VII. Claim 17, drawn to a *library* of proteins, wherein said proteins each contain a binding site that binds to a MPBD and wherein said proteins have been fused to at least one copy of an antigenic epitope of 6-20 amino acids that binds to an antibody, classified in class 424, subclass 192.1.

VIII. Claim 18, drawn to a *library* of nucleic acids encoding proteins that contain MPBD and fused to a single chain antibody, classified in class 424, subclass 134.1.

IX. Claim 19, drawn to a *library* of nucleic acids encoding proteins, wherein said proteins each contain a binding site that binds to a MPBD and wherein said proteins have been fused to at least one copy of an antigenic epitope of 6-20 amino acids that binds to an antibody, classified in class 424, subclass 192.1.

X. Claims 20-22, drawn to an assay for determining the activity of a protein-protein interaction comprising transforming a cell by a vector containing a gene encoding a fusion protein comprising a protein containing a MPBD

that is substituted by a single chain antibody and / or transforming a cell by a vector containing a protein containing a binding site that binds to a MPBD, wherein a linear epitope that binds to the MPBD within the binding site is substituted by at least one antigenic epitope that binds to an antibody, classified in class 435, subclass 7.1.

XI. Claim 23, drawn to an assay for determining the activity of a protein-protein interaction comprising transforming a cell by vectors containing nucleic acid sequences selected from a nucleic acid *library* encoding fusion proteins that comprise a MPBD that is substituted by a single chain antibody and / or transforming a cell by vectors containing nucleic acid sequences selected from a nucleic acid *library* encoding proteins containing a binding site that binds to a MPBD, wherein a linear epitope that binds to the MPBD within the binding site is substituted by at least one antigenic epitope that binds to an antibody, classified in class 435, subclass 7.1.

XII. Claim 24, drawn to an assay for testing for molecules that interact with a protein-protein complex, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV, VI-IX and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

MPEP § 808.01). In the instant case the different inventions have not been disclosed as capable of use together and the cells of Invention V have a different function and effect by virtue of their structural differences, including two different nucleic acid vectors, from the proteins and the nucleic acid encoding different fusion proteins of Inventions I-IV and VI-IX.

Inventions I-IV and VI-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have not been disclosed as capable of use together and the libraries of Inventions VI-IX have different functions and effects by virtue of their multiple, iterative, and varied molecular structure from fusion proteins and the genes that encode them, and vectors thereof, of Inventions I-IV.

Inventions I, III and II, IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because Inventions I and III comprise proteins, which have a different molecular structure from the nucleic acid genes of Inventions II and IV.

Inventions I and III are unrelated. In the instant case the fusion proteins comprising a protein containing a modular protein binding domain (MPBD), wherein the MPBD is substituted by a single chain antibody of Inventions I, have different modes of operation and effects by virtue of their different molecular structures and peptide

sequences from the fusion proteins comprising a protein containing a binding site that binds to a MPBD, wherein a linear epitope that binds to the MPBD within the binding site is substituted by at least one antigenic epitope that binds to an antibody of Inventions III.

Inventions II and IV are unrelated. In the instant case the genes encoding fusion proteins comprising a protein containing a modular protein binding domain (MPBD), wherein the MPBD is substituted by a single chain antibody and vectors thereof, of Inventions II, have different modes of operation and effects by virtue of their different molecular structures and nucleic acid sequences from the genes encoding fusion proteins comprising a protein containing a binding site that binds to a MPBD, wherein a linear epitope that binds to the MPBD within the binding site is substituted by at least one antigenic epitope that binds to an antibody of Inventions IV.

Inventions VI-VII and VIII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have not been disclosed as capable of use together and the protein libraries of Inventions VI-VII have different functions and effects by virtue of their different molecular structure from the nucleic acid libraries of Inventions VIII-IX.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions have not been disclosed as capable of use together and the libraries of proteins that contain MPBD and are fused to a single chain antibody of Invention VI, have different functions and effects by virtue of their different molecular structure from the libraries of proteins, wherein said proteins each contain a binding site that binds to a MPBD and wherein said proteins have been fused to at least one copy of an antigenic epitope of 6-20 amino acids that binds to an antibody of Invention VII.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have not been disclosed as capable of use together and the libraries of nucleic acids that encode a MPBD fused to a single chain antibody of Invention VIII, have different functions and effects by virtue of their different molecular structure from the libraries of nucleic acids encoding proteins that each contain a binding site that binds to a MPBD and wherein said proteins have been fused to at least one copy of an antigenic epitope of 6-20 amino acids that binds to an antibody, of Invention IX.

Inventions I-IX and X-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inventions of

I-IX may be used for the production and isolation of the gene fusion protein products for *in vitro*, cell-free assays.

Inventions I-IX and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inventions of I-VII may be used for the production and isolation of the gene fusion protein products for assays that occur in the living cell.

Inventions X-XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, because Inventions X-XI are performed in living cells but Invention XII is performed outside the living cell.

Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation and effects because the invention of claim XI comprise vectors of nucleic acid libraries, which contain a diverse mixture of nucleic

acids and thereby have a different structures from non-library nucleic acids and vectors of Invention X.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species

2. Claim 2 is generic to a plurality of disclosed patentably distinct species comprising src homology 2, src homology 3, phosphotyrosine binding, WW, PDZ, 14.3.3., WD40, EH or Lim. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention and species to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
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